IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: Ethicon Wave 1 cases listed in Exhibit A	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DENISE ELSER, M.D.

Plaintiffs respectfully request that this Court preclude defense expert Denise Elser, M.D., a urogynecologist, from giving opinions on: (1) the adequacy of Defendants' product warnings and instructions for use ("IFU"); (2) the design and materials of Defendants' transvaginal mesh products at issue, including the safety and efficacy of those devices; and (3) her statements about the safety and efficacy of Defendants' products based on her own practice.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, "the district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues

in the case.'" *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony "must be supported by appropriate validation—i.e., 'good grounds,' based on what is known. In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

There are five factors courts often consider, taken from the *Daubert* opinion, in assessing the reliability of expert testimony:

- (1) whether the testimony has been tested,
- (2) whether it has been published or exposed to peer review,
- (3) its rate of error,
- (4) whether there are standards and controls over its implementation, and
- (5) whether it is generally accepted.

See Cavallo v. Star Enterprise, 100 F.3d 1150, 1158 (4th Cir. 1996). However, "the factors discussed in *Daubert* were neither definitive, nor exhaustive." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because "*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder." *Cavallo*, 100 F.3d at 1158.

ARGUMENT

This Court should prohibit Dr. Elser from giving the opinions referenced above because she is not qualified to opine on those issues and has not done the necessary research to produce opinions that can reliably be applied to this case.

Dr. Elser has issued a report in this litigation addressing the TVT and TVT-O "subject products." (General TVT & TVT-O Expert report of Denise M. Elser, M.D. ("TVT Report"), attached as Exhibit B). This report contains the following general opinions:

- The IFU and/or the warnings concerning Defendants' subject products are adequate in providing information concerning the potential risks of the TVT and TVT-O to the intended users. (*Id*. at 39).
- Defendants' products at issue are not defective, but are safe and effective for their intended use and have a good safety profile. The benefits of Defendants' products outweigh the risk of using the products, and they are safer and better than alternative surgeries. The products at issue use the most suitable mesh for treating SUI . (*See id*. at 19, 35, 25, 36).
- Her practice's sling revision rate for either exposure or incomplete bladder emptying is 4.5%. (*See id*. at 2).

The first bullet point contains an opinion expressly directed to the adequacy of the warnings and IFU accompanying the subject products.

The second bullet point clearly states an opinion about the subject products' design. That opinion merely substitutes the words "safe and effective" in place of "reasonably safe for its intended use" which is the legal test on a design defect claim in West Virginia. *See Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 683 (W. Va. 1979) (stating that "the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use"). Additionally, it addresses the risk-utility test, which is part of the inquiry into a design defect claim. *See, e.g.*, *Beard v. Johnson & Johnson, Inc.*, 41 A.3d 823, 836 (Pa. 2012); *Branham v. Ford Motor Co.*, 701 S.E.2d 5, 14 (S.C. 2010); *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 352 (Ill. 2008), *opinion modified on denial of reh'g* (Dec. 18, 2008); *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 258 (Tex. 1999); *Halliday v. Sturm, Ruger & Co.*, 792 A.2d 1145, 1150 (Md. Ct. App. 2002); *Cavanaugh v. Skil Corp.*, 751 A.2d 564, 580 (N.J. Super. App. Div. 1999), *aff'd*, 751 A.2d 518 (N.J. 2000).

The final bullet point relates to Dr. Elser's attempt to bolster the safety and efficacy of Defendants' products without proper foundation or analysis, by offering conclusions regarding an entire class of medical devices based upon her personal experience in her practice, without providing any data regarding the products at issue. As discussed in greater detail below, this is Dr. Elser's attempt to backdoor into evidence an improper and unsupported opinion on her personal complication rate.

For the reasons below, Elser should not be permitted to give those opinions under the standards set by Rule 702 and *Daubert*.

I. DR. ELSER'S OPINION ON THE ADEQUACY OF DEFENDANTS' WARNINGS SHOULD BE EXCLUDED PURSUANT TO DAUBERT.

Dr. Elser's opinions on the adequacy of Defendants' warnings are based on precisely the *ispe dixit* that the Supreme Court has found inadmissible. Dr. Elser admits she is wholly

unaware of any standards governing warnings. She admits she engaged in no research on any criteria for warnings. She testifies that objective criteria are immaterial to her. She is testifying solely based on her status as a surgeon and thus her knowledge of what a surgeon needs to know. Federal courts consistently find opinions based on such subjective feelings and knowledge unreliable, and therefore inadmissible, largely because it is impossible to evaluate their reliability.

Federal courts agree that *ipse dixit* opinions—which are justified solely by the fact that the expert holds them—are inadmissible. *See, e.g.*, *GE v. Joiner*, 522 U.S. 136, 146 (1997); *Holesapple v. Barrett*, 5 Fed. Appx. 177, 2001 WL 208490, at *2 (4th Cir. March 2, 2001) ("[I]t still is a requirement that the expert opinion evidence be connected to existing data by something more than the 'it is so because I say it is so' of the expert."); *Pampered Chef v. Alexanian*, 804 F. Supp. 2d 765, 794 (N.D. Ill. 2011) ("If admissibility could be established merely by the *ipse dixit* of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong.").

This Court has also excluded *ipse dixit* opinions in this transvaginal mesh litigation, and other product liability litigations. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 603 (S.D.W. Va. 2013) (excluding testimony where expert's "opinions are simply *ipse dixit* opinions"). *See also, e.g., In re Digitek Prods. Liab. Litig.*, 821 F. Supp. 2d 822, 840 (S.D. W. Va. 2011) (Goodwin, J.) ("Dr. Mason's reason for using the long-delayed draw in his analysis is this: '[I]t's what I've got. And that's the way I'm doing it.' That is ***ipse dixit*** condemned by *Daubert* and its progeny."); *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680814, at *6 (S.D. W. Va. July 8, 2011) (excluding expert testimony because of the analytical gap between the data and opinions derived).

Dr. Elser has admitted that her opinions regarding the adequacy of Defendants' warnings are not based on any objective standards. In fact, she has no criteria of any kind:

> Q. Well, as you sit here now do you have an understanding of any standard whatsoever from any source as to what risks and complications are supposed to be disclosed in an IFU [Instructions for Use]?
>
> A. No.
>
> [Def. lawyer]: Object to the form.
>
> Q. When you're giving your opinions as to whether or not the IFU adequately warns of risks and complications, you're just basing that on your own opinions based on your own experience and what you think is reasonable. Is that fair?
>
> A. That's fair.
>
> Q. You're not relying on any objective standard from any source, correct?
>
> A. Correct.

(Elser Deposition, Sept. 16, 2014, portions attached as Exhibit C, at 37:4-19).

Dr. Elser not only admits that her opinions are not based on any standard, she also acknowledges she has no idea whether FDA standards even exist in this context:

> Q. Are you aware of whether there are FDA regulations which provide for what type of information is supposed to be provided in an IFU?
>
> A. No.

(*Id*. at 38:8-11).

> * * *
>
> Q. Have you looked at any internal documents at all, whether it's an e-mail, whether it's a deposition, anything, from Ethicon or any testimony from anyone in Ethicon, regarding what FDA regulations would require to be disclosed in an IFU?
>
> A. No.

(*Id*. at 38:12-18).

Dr. Elser admits she has no knowledge of the regulatory or industry requirements relating to Defendants' obligations to warn:

> Q. Once the IFU is out there, if Ethicon learned of a risk or complication that was not previously warned about and it was a significant risk or complication in terms of the harm it could cause to a woman, do you know whether or not Ethicon had any obligation or have any opinion whether they had any obligation to get that information out to doctors?
>
> A. I don't know what the obligations are. So, do they get – would it be updated on a regular time interval or is it depending on when complications happen?
>
> Q. Again, in forming your opinions, you don't know what Ethicon's obligations were to warn, correct?
>
> A. Correct.

(*Id*. at 167:14-168:4).

Dr. Elser admits she made no inquiry into Ethicon's internal requirements to determine, at the very least, whether Ethicon had satisfied its own protocols for providing adequate information to physicians:

> Q. Have you made any effort to corroborate your own opinion as to what needs to be in a warning in an IFU by looking to what Ethicon's professionals believed needed to be in there just so you could see whether the standard you were applying was consistent with someone in the medical device industry would apply. Did you ever do that?
>
> A. No.
>
> [Def. counsel]: Object to form.

(*Id*. at 37:22-38:6).

Dr. Elser admits she has no idea what risks were known to Defendants during the relevant time period:

> Q. Is it fair to say you have no idea what complications and risks were known to Ethicon Medical Affairs and when they were known?

A. That would be fair.

(*Id*. at 42:3-43:1).

Dr. Elser admits her opinion is based solely on her own subjective beliefs:

Q. Earlier you told me what you expected to see in an IFU. That's – is it fair to say that's the standard you applied as to what you think needs to be disclosed in an IFU?

[Def. counsel]: Object to form.

A. Yes.

(*Id*. at 38:23-39:4).

In other words, her opinion is the very "it is so because I say it's so" *ipse dixit* testimony that *Daubert* was intended to prevent.[1] In addition, Dr. Elser admits she engaged in no analysis to determine whether her self-made standards are consistent with those of anyone else:

Q. Have you ever studied the question of what information needs to be in an IFU, have you ever engaged in any study of that question?

A. No, I have not.

Q. Have you ever made an effort to confirm that your understanding for what needs to be in an IFU is consistent with what other doctors believe should be in an IFU. Have you ever studied that question?

A. No, I have not.

(*Id*. at 41:9-18).

Dr. Elser's admits she has no idea what is required to be an IFU or product warning by any standard. She did no research or analysis on the subject. Dr. Elser admits that her opinions are based on nothing more than her subjective views. Those opinions are thus inadmissible under the *Daubert* line of cases.

[1] "*Ipse dixit*" is "a statement relying for truth upon the fact it has been said: and which is not independently justified or corroborated." JOHN GRAY, LAWYER'S LATIN: A *VADE-VECUM* 76 (2002).

II. DR. ELSER SHOULD BE PRECLUDED FROM GIVING DESIGN OPINIONS.

a. Dr. Elser has expressly testified that she is not a design expert or materials expert

As a primary issue, Dr. Elser should be precluded from opining about the design of the subject products, including offering opinions on the most suitable mesh for the treatment of SUI, because she admits she is not an expert on design of medical devices or mesh materials:

Q. Do you consider yourself an expert in the design of medical devices?

A. No.

(Denise Elser Deposition, Nov. 5, 2015, portions attached as Exhibit D, at 35:15-17).

Q. You don't consult as a materials expert, correct?

(by defense counsel) Form.

A. That is correct.

Q. And you have never designed a mesh, correct?

A. No.

(*Id*. at 128:23-129:8).

This Court has previously recognized the importance of an expert's admission that he is not an expert. In the *Bard* litigation, this Court precluded Dr. Shull from giving warnings opinions because he had testified that "I would not claim to be an expert in that area." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). That same analysis applies here to Dr. Elser, who admitted during her deposition that she is not an expert on design or materials selection. As such, she should be precluded from giving any opinions related to design of the subject products.

b. Dr. Elser did not review Defendants' key documents related to product design, and even if she had reviewed them, Dr. Elser has no base of knowledge as to what those documents would demonstrate.

Dr. Elser should also be precluded from opining about the design of the subject products because she has not reviewed Defendants' internal documents about the design process. This Court has recognized the importance of reviewing internal documents in giving opinions about the design of medical devices. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015) (excluded plaintiffs' expert who "reached opinions on the improper design of the Uphold without having first considered BSC's design protocols"). This Court reasoned that "regardless of the literature he has reviewed or the experience he has gained, a necessary piece of data remains missing from Dr. Shull's methodology. Without any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures from the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

Similarly, Dr. Elser confirmed that she did not review Defendants' internal operating procedures or any other internal design documents in formulating her opinions:

> Q. Doctor, do you know what the standard is that a manufacturer must follow in designing mesh products?
>
> A. No.
>
> Q. Do you know what responsibilities a manufacturer holds in designing mesh products?
>
> (by defense counsel) Object to form.
>
> A. No.

(Denise Elser Deposition, March 30, 2016, at 57:6-19, portions attached as Exhibit E).

> Q. Do you know what a design failure modes effects analysis is?

A. No.

(Denise Elser Deposition, April 24, 2014, at 119:19-21, portions attached as Exhibit F).

> Q. Just to be clear, you have not asked to see any internal Ethicon or Johnson & Johnson company documents in order to form your opinions in this case regarding the TVT and TVT-O, correct?
>
> A. That's correct.
>
> Q. You didn't feel there was anything in Ethicon or Johnson & Johnson's internal files that could be helpful to you in reaching your opinions in this case on whether or not the TVT or the TVT-O is defectively designed?
>
> (by defense counsel) Object to form.
>
> A. Correct.

(Elser Dep., March 30 2016, Ex. E, at 26:21-27:9).

Dr. Elser has confirmed that she does not even know what a design failure modes effects analysis is. (Elser Dep., April 24, 2014, Ex. F, at 119:19-21). As discussed in the deposition of Defendants' medical director Charlotte Owens, the purpose of a design failure modes and effects analysis ("dFMEA") is to "review the potential risk associated with the design of the product." (Charlotte Owens Deposition, Sept. 13, 2012, at 485:14-24, portions attached as Exhibit G).[2]

> Q. And when you say "associated with the design of the product," that means that when the product is in a woman's body and the product was manufactured completely consistent with the specifications, these are the things that could go wrong and harm a patient, correct?
>
> A. Correct.

(*Id.* at 485:25-486:7).

> Q. And you understood that it was required that you capture all of the different failure modes, all the things that could go wrong in the procedure, even if the doctor was properly trained and following the proper procedure, and the effects of those failure modes, the hazards that could occur, and the resulting harms, and you were supposed to capture all of them, correct?

[2] Ms. Owens's cited deposition related to the Prolift product only, but the discussion quoted was not product-specific.

A. Yes, all that we could conceive of, yes.

(*Id*. at 449:12-22).

Dr. Elser should have reviewed these documents in forming her opinions about the design of the subject products. But not only did she fail to review those documents, she did not even know what the phrase "design failure modes and effects analysis" means. (Elser Dep., April 24, 2014, Ex. F, at 119:19-21). Because she did not review the relevant design documents, Dr. Elser lacks the required knowledge to give a reliable opinion about the design or materials selection of Defendants' transvaginal mesh products.

Based on the foregoing, Dr. Elser's opinions on the issue of product design and mesh material selection should be excluded.

III. DR. ELSER'S OPINION ABOUT HER PERSONAL EXPERIENCE RELATED TO THE SAFETY AND EFFICACY OF THE TVT AND TVT-O SHOULD BE EXCLUDED BECAUSE THEY ARE NOT BASED ON ANY OBJECTIVE STANDARD, AND HER ANALYSIS AND METHODOLOGY ARE FLAWED

Dr. Elser should be precluded from testifying about her perceived safety, efficacy, and patient satisfactions rates with the subject products from her practice. Such opinions are entirely unsupported by any reliable methodology, nor have they been subject to peer review. For example, Dr. Elser has stated in her expert report that her practice's sling revision rate for either exposure or incomplete bladder emptying is 4.5%. (Elser TVT Report, Ex. B, at 2). However, there is no foundation, reliable data, or verifiable methodology provided for this opinion, as demonstrated by Dr. Elser's testimony:

Q. How did you arrive at that 4.5 percent?

A. I don't remember which dates I pulled the data on a substantial number of slings in our practice and then tracked how many of those over a certain period of time when back for reoperation.

Q. Okay, what period of time did that cover?

A. I don't remember. I believe it was at least a year.

(Elser Dep., Nov. 5, 2015, Ex. D, at 23:15-24).

Q. But you can't tell me that today. I mean, how many patients did you look at in total?

A. I don't remember.

(*Id*. at 25:5-7).

Dr. Elser's opinions about complication rates among her own patients are inappropriate, unsupported, and inadmissible. She lacks any reliable methodology or analysis to support her conclusions. Further clouding her analysis is the inclusion of other slings in Dr. Elser's practice, which distort the clinical results she reports from her personal experience, and would confuse and mislead the jury as to success and complication rates of the products at issue—the TVT and TVT-O. This distortion of clinical results in her opinions is demonstrated by her testimony:

Q. All right. Just to be clear, so the 4.5 percent reoperation rate you referred to in your report, that refers to sling products, or dies that also include other mesh products

A. That was slings.

(*Id*. at 26:4-8).

Q. Okay. So this 4.5 percent would not relate to the TVT retropubic product, correct?

A. I don't think so.

Q. It could include Boston Scientific or AMS products as well, correct?

A. Correct.

(*Id*. at 63:22-25, 64:4-6).

Dr. Elser's own testimony indicates that the only numerical rate she is able to express is a re-operation rate for either exposure or incomplete bladder emptying. By her own admission, she includes other slings in her analysis and does not know how many patients are included in the analysis. She also admits that it does not relate to the TVT-Retropubic product.

Dr. Elser is asserting and relying on alleged safety and efficacy data from her own practice, and yet she has no foundation whatsoever for that assertion. She only tracks re-operation rates, but even for that metric, does not track the time frame, or even the particular type of mesh product removed As such, Plaintiffs have no reasonable way of testing the veracity of Dr. Elser's claims. In addition, allowing Dr. Elser to offer an opinion as to her re-operation rate for all slings would be confusing and misleading to a jury when considering the question of whether or not the TVT and TVT-O devices are defective. Such opinions should be excluded under Rule 403. Because there is no foundation for her opinions, Dr. Elser should be prohibited from providing this testimony.

CONCLUSION

Based on the foregoing, Dr. Elser should be precluded from giving opinions on (1) the adequacy of Defendants' product warnings and instructions for use ("IFU"); (2) the design and materials of Defendants' transvaginal mesh products at issue, including the safety and efficacy of those devices, and (3) her statements about the safety and efficacy of Defendants' products based on her own practice.

Dated: April 21, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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